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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,997	07/26/2001	Donald W. Petersen	06317-038002	1532

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EXAMINER
WITZ, JEAN C

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/13/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,997	PETERSEN ET AL.	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 31-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 31-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Numbering

The numbering of claims of the amendment was not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). In this case, claims 16-30 had been cancelled in a preliminary amendment. The newly presented claims were improperly numbered 16-27 and have been renumbered 31-42. Applicants are advised to refer to these claims in future communications with the office with their proper numbers.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Yim et al. (5,385,887) for the reasons of record.

Applicants assert that the inclusion of the other ingredients would materially affect the claimed compositions because "the claimed composition could not be used as a versatile base." Such an argument is not deemed persuasive since the evaluation of

the invention as claimed under the statute is based upon how the additional ingredients listed in the patent reference materially affect the basic characteristics of the claimed components. Arguments of intended use fail to impart any basis for patentability to an old composition.

As stated in the previous office action, If Applicants contend that additional materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). In this case, Applicants' own specification teaches that other ingredients such as disclosed by the composition in the patent reference are specifically intended to be included with the claimed composition including demineralized bone matrix, bone morphogenic proteins and any number of other ingredients such as listed at page 4 of the specification. The composition of Yim et al. teaches a bone graft composition that contains calcium sulfate, specifically calcium sulfate hemihydrate, a mixing solution which may be water or a sodium chloride solution (among others), bone morphogenic proteins, a polymer matrix component to provide a scaffolding for the bone morphogenic proteins and what Yim et al. calls a "protein-sequestering material". This material is identical to what Applicants call their "plasticizing substance". The "protein-sequestering material" is included to "hold" the bone morphogenic protein at the site in need of the bone morphogenic protein, i.e. the site of the bone defect or injury. Basically, the "protein-sequestering material" acts to

increases the viscosity of the composition thereby reducing the rate of diffusion of the bone morphogenic proteins from the site of bone defect or injury but will also inherently act to "plasticize" the composition, i.e. give it a specific viscosity and flowability.

Therefore, arguments of what else Applicants intend to add to the claimed composition may be taken to indicate that a composition such as disclosed by the Yim reference falls within the scope of the instant claims and therefore anticipates them.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sander et al. (5,356,629) combined with Hanker et al. (4,619,655).

Applicants point to the fact that Sander does not specifically use calcium sulfate hemihydrate in his invention for issues related to length of time of workability and length of time until resorbtion as evidence of "teaching away" from the addition of calcium sulfate hemihydrate to the composition of Sander.

However, it is clear that Sander et al. teach that the biocompatible particles may be bioresorbable or nonbioresorbable and Sander et al. acknowledge in the Background of the Invention that plaster of paris (calcium sulfate hemihydrate) is known as a bioresorbable substance is conventionally used as a bone graft material. Applicants' arguments fail to take into consideration the state of the art with respect to the use of calcium sulfate hemihydrate at the time the invention was made and fail to address the fact that the teachings of both references taken as a whole must be considered.

Hanker et al. teaches that calcium sulfate hemihydrate is a conventional material used as a bone implant. It is mixed with water and is applied to the damage or defect in the bone. The calcium sulfate hemihydrate, upon hydration, hardens in the area of implantation and acts both as a source of calcium for bone growth in the area of the implant, acts as a support for the damaged area during the time of repair, and stimulates revascularization and bone formation.

As stated in the previous office action, one of ordinary skill in the art at the time the invention was made would have been motivated to add calcium sulfate hemihydrate to the composition of Hanker depending upon the desired result of the bone implant based upon the specific circumstances. It is noted that Sander et al. provides a non-limiting list of embodiments for potential resorbable additives (the teaching of a U.S.

patent is not limited to its recitations of preferred embodiments) and, more importantly, provides no explicit proscription against its use. Again, as noted in the previous office action, insofar as the statements cited by Applicants found at column 1, lines 30-38 of the Sander et al. patent are asserted be a teaching away from the use of calcium sulfate hemihydrate, it is clear from the teaching of Hanker et al. at col. that both workability and resorbability of a calcium sulfate hemihydrate may be adjusted by adjusting the density of the calcium sulfate hemihydrate to obtain any desired set time and resorption rate. Further, it is exactly the teaching of Sander et al. that motivates the addition of a matrix such as claimed to a calcium sulfate hemihydrate bone graft composition because it is taught to improve the workability. Further, there may certainly be circumstances where a reduced resorbtion rate may be desired due to the extended need for support in the graft area.

With regard to the proscriptions of claims 12 and 13 against the inclusion of bone and a polymer matrix, since the compositions of both Hanker et al. and Sander et al. are disclosed as functional and suitable for the purpose of a bone graft composition, the practitioner would not need any further components. Finally, with regard to claims 14 and 15 which recite specific amounts of each component, it is noted that per claim 15, the calcium sulfate is present in an amount that comprises 72% of the composition, the plasticizing solution is present in an amount that comprises approximately 4% of the composition and the wetting solution is present in an amount that comprises 24% of the composition. Sander et al. teach that the bioresorbable component is present in the unwetted state from about 64 – 94% and that the matrix is present in the composition in

the unwetted state from about 6 – 36% of the composition. After being wetted, the composition preferably comprises 35 – 75% bioresorbable component and the matrix preferably comprises 5 – 20% of the composition. Since the physical properties of both the calcium sulfate and the plasticizing (matrix) substances are well known and since the references teach that determining the desired time and degree of workability for the specific bone defect or damage is well within the skill of the practitioner, it would have equally been well within the skill of the practitioner at the time the invention was made to engage in a reasonable and not undue amount of experimentation to determine a desired recipe for a bone graft composition containing calcium sulfate, a plasticizing substance as disclosed and the amount of wetting solution required, particularly since the amounts claimed are either well within the ranges disclosed or extremely close, as in the case of the ranges taught for the matrix component. It is also noted that the patent uses the term "about" which indicates that there is at least some leeway in the amounts taught to be effective.

Finally, arguments with regard to the intended use of the composition as a "customizable base" suffer from the same defects as those presented in the rejection recited above. Each of the components taught by the patent references are clearly well known for their individual contribution to the activity of the composition. Applicants' arguments are drawn to the inclusion of ingredients in the patent references that are asserted to be omitted by the use of the transitional phrasing in the claims. However, Applicants' own specification indicates that these very same ingredients are intended to be added to the composition, as desired or required by the particular condition and/or

location to be treated. Therefore, it is clear that a practitioner in the art is clearly aware of the activity of all of the components conventionally used in a bone graft composition and it is clearly within the skill of said practitioner to customize a bone graft composition with desired ingredients while omitting others that are not appropriate for a specific treatment condition and/or location. As a result of the extensive disclosure and knowledge in the state of the art regarding each of these components, it is lastly clear that the customization of this composition is performed without undue experimentation and results in reasonable expectation of success that the customized composition will perform as desired.

Claims 31-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Yim et al. (5,385,887), Sander et al. (5,356,629) and Hanker et al. (4,619,655) taken for what they represent in the art as a whole.

Applicants' newly presented claims now recite closed transitional phrasing to further limit the composition presented in claims 1-15. The only ingredients present are the calcium sulfate hemihydrate, the plasticizing substance and the mixing solution. Of these three ingredients, Hanker teaches two – the calcium sulfate hemihydrate and the mixing solution – that are successfully used by themselves as a bone graft. Hanker teaches that calcium sulfate hemihydrate is a conventional material used as a bone implant. It is mixed with water and is applied to the damage or defect in the bone. The calcium sulfate hemihydrate, upon hydration, hardens in the area of implantation and acts both as a source of calcium for bone growth in the area of the implant, acts as a support for the damaged area during the time of repair, and stimulates revascularization

and bone formation. Yim et al. specifically includes calcium sulfate hemihydrate for its known benefits. Yim states that calcium sulfate hemihydrate "reduces set up time and provides improved moldability and consistency of the resulting formation." As a result, it is clear in the state of the art that the both the set time and the consistency, i.e. workability, of calcium sulfate hemihydrate can be adjusted by the addition of a plasticizing agent in specific situations where such a workability are required.

One of ordinary skill in the art would have been motivated to improve the workability of the composition of Hanker by the addition of the plasticizing substance disclosed by both Sander and Yim because each of the components in the claims are clearly disclosed and well known for their individual contribution to the activity of the composition. Therefore, a practitioner in the art is clearly aware of the activity of all of the components conventionally used in a bone graft composition and it is clearly within the skill of said practitioner to customize a bone graft composition with desired ingredients while omitting others that are not appropriate for a specific treatment condition and/or location. As a result of the extensive disclosure and knowledge in the state of the art regarding each of these components, it is lastly clear that the customization of this composition is performed without undue experimentation and results in reasonable expectation of success that the customized composition will perform as desired.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 3, 8 and 12-38 of copending Application No. 09/327761 for the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jean C. Witz
Primary Examiner
Art Unit 1651

August 12, 2002